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(72) Inventors; and

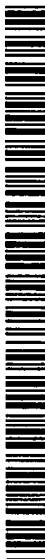
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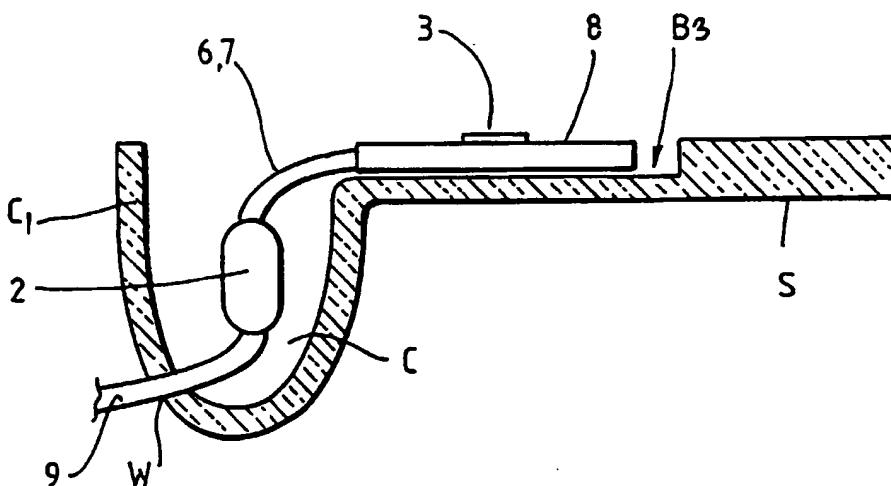
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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: IMPROVED COCHLEAR IMPLANT PACKAGE



WO 01/10369 A1



(57) Abstract: An implant package for a cochlear implant, including stimulator electronics contained within a protective housing (2) and being coupled to an electrode array (9) for insertion into the cochlea of a patient, and being further coupled to a receiving and/or transmitting coil (8) enclosed within a protective casing, said protective housing being dimensioned and shaped to be capable of location within the mastoid cavity (C) of the patient nearer to the entry point of the electrode array to the cochlea, said further coupling being contained in a flexible connection between the protective housing (2) and the protective casing (8).

IMPROVED COCHLEAR IMPLANT PACKAGE

Field of the Invention

This invention relates to improvements in cochlear implants, and more particularly to improvements relating to the shapes of implant packages, e.g. 5 receiver-stimulator packages, to enable the cochlear implant to be positioned in a patient in a more desirable location than the location presently used.

Background of the Invention

Present cochlear implant receiver-stimulators are placed in a patient by 10 drilling a bed into and through the posterior section of the mastoid bone lying behind the ear. The bed is usually made by drilling the bone down to the lining of the brain or dura mater. The receiver-stimulator of the Nucleus cochlear implant made by Cochlear Limited has a receiver-stimulator package made from titanium which houses the stimulation electronics and which is fitted into the 15 bed in the mastoid bone. A receiver coil extends from the back end of the package and lies superficial to the bone. Other cochlear implants have included packages made from ceramic material and these are usually placed completely within a bed drilled down to the lining of the brain, especially in young children.

20 In young children, placing either of the above packages in the mastoid bone some distance behind the ear can lead to the packages creating an external swelling, which can be unsightly. More importantly, such placements of the package can lead to serious damage caused by excessive impact to the head in the area adjacent the implant. Such impact can lead to fractures of the electrode 25 where it exits the package, or cracking or damage of the package itself. In addition, because the packages are placed in this particular location, especially where a bed is drilled down to the lining of the brain, it is possible for excessive impact to cause the package to enter the cranial cavity and damage structures including the brain.

- 2 -

Summary of the Invention and Object

It is an object of the present invention to provide an improved implant package for a cochlear implant shaped to be received in a more desirable location within the skull of the patient.

5 The invention provides an implant package for a cochlear implant, said implant package including stimulator electronics contained within a protective housing and being operably coupled to an electrode array adapted for insertion into the cochlea of the patient, and being further operably coupled to a receiving and/or transmitting coil enclosed within a protective casing, said protective
10 housing being dimensioned and shaped to be capable of location within the mastoid cavity of the patient nearer to the entry point of the electrode array to the cochlea, said further coupling being contained in a flexible connection between the protective housing and the protective casing.

By positioning the implant electronics housing in this way, the housing is
15 less exposed to the risk of trauma caused by excessive blows to the head as it lies below the surface of the skull bone and is therefore less susceptible to a direct blow, and is additionally protected by the overlying pinna. The flexible coupling enables the coil to be placed in an optimal position and, depending on the anatomy and the age of the person, over time the coupling would adjust to
20 any changes in head shape.

Advantageously, the implant package is electrically coupled to the electrode array and is further electrically coupled to the receiving and/or transmitting coil.

In a preferred form, the flexible coupling is made from a material having
25 memory so that the coupling retains its desired shape when installed in the mastoid cavity. The flexible connection can include one or more flexible arms which contain the electrical leads for connecting the implant electronics in the protective housing to the transmitter/receiver coil. While two arms are shown in the preferred embodiment, one arm may have the advantage of reducing the
30 inductive effects between the leads within the arms and the magnetic coil of the transmitter/receiver.

- 3 -

The implant package is preferably a receiver-stimulator package for a cochlear implant.

Brief Description of the Invention

5 A preferred embodiment of the invention will now be described with reference to the accompanying drawings in which:

Figure 1 schematically illustrates one embodiment, and

10 Figure 2 is a schematic cross section illustrating the positioning of the protective casing and the protective housing relative to the ear canal, the mastoid cavity and the drilled bed in the skull.

Description of the Preferred Embodiment

Anatomical dissections show that there is a gutter lying between the sigmoid sinus, posterior osseous ear canal, the mastoid tip and the floor of
15 middle fossa where an appropriately shaped housing for the implant unit can be placed so that the housing is not exposed above the surface of the bone.

As illustrated in the drawings, the housing 2 comprises a narrow elongate rectangular housing having rounded ends, somewhat like a flattened ovoid or lozenge shape, which is received in the mastoid cavity C referred to above
20 adjacent the ear canal C₁. The housing 2 may be made from titanium, similar to the Nucleus device, or from cast or moulded ceramic material.

As described above, the protective housing 2 for the implant electronics, in this case the receiver-stimulator electronics, is connected by suitable leads 4, 5 to a transmitter/receiver coil 3, the leads 4, 5 being contained within flexible
25 arms 6, 7 of inert material such as silicone rubber. If desired, the arms 6, 7 can be formed from or incorporate a material having memory so that the arms retain their manufactured shape after installation.

The coil 3 is enclosed within a protective casing 8, which is received in a drilled bed B₃ in the mastoid bone behind the ear. Suitably shaped beds B₁, B₂
30 connecting the mastoid cavity and the drilled bed B₃ with the skull S receive the flexible arms 6, 7 containing the connecting leads 4, 5. A further lead 9 extends

- 4 -

from the housing 2 into the ear canal C₁ through a window W and terminates in an electrode array (not shown) which is implanted in the cochlea.

Since the receiver-stimulator housing 2 is located in the mastoid cavity C, below the surface of the bone, it is less susceptible to damage and is
5 protected and hidden by the overlying pinna. The flexible arm(s) 6, 7 allow optional positioning of the coil and permit changes in head shape.

The receiver-stimulator electronics, the transmitter/receiver coil, and the electrode array for implantation in the cochlea of the patient are configured in accordance with the patent literature relating to the cochlear implant technology
10 and do not form any part of the present invention.

While one preferred shape for the protective housing has been described above, it will be appreciated that different shapes, which are capable of lying wholly within the gutter forming part of the mastoid cavity, can be adopted without departing from the essence of the invention defined above.

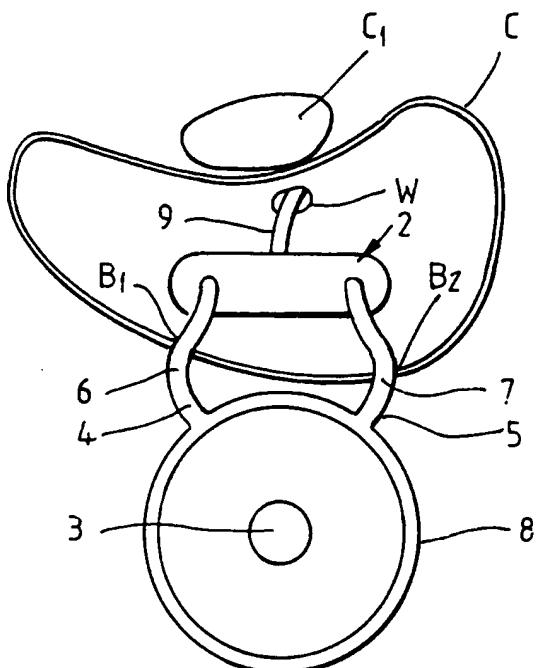
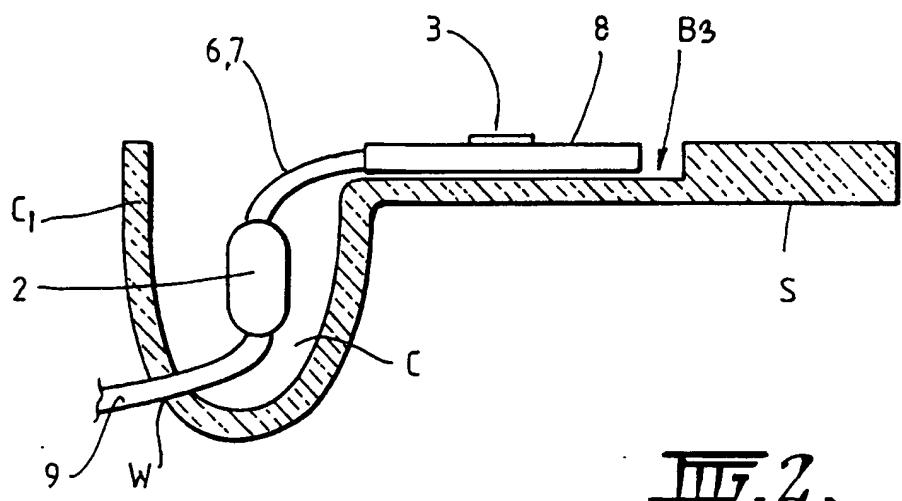
15 It is also envisaged that whilst the above embodiment is described with reference to a conventional cochlear implant system, i.e. one with a receiver-stimulator that receives coded signals from an external unit and provides stimulation to the cochlea accordingly, the present invention could equally be applied to a totally implanted cochlear implant system. In such a system the
20 implant unit has the capability of functioning without the need for any external devices, at least for a defined period of time.

- 5 -

CLAIMS:

1. An implant package for a cochlear implant, said implant package including stimulator electronics contained within a protective housing and being operably coupled to an electrode array adapted for insertion into the cochlea of the patient, and being further operably coupled to a receiving and/or transmitting coil enclosed within a protective casing, said protective housing being dimensioned and shaped to be capable of location within the mastoid cavity of the patient nearer to the entry point of the electrode array to the cochlea, said further coupling being contained in a flexible connection between the protective housing and the protective casing.
2. The implant package of claim 1, wherein the flexible connection facilitates optimal positioning of the coil, depending on the anatomy and age of the patient.
3. The implant package of claim 1 or 2, wherein the flexibility of the flexible connection between the protective housing and the protective casing is such as to allow changes in head shape as the patient grows.
4. The implant package of any preceding claim, wherein the flexible connection is made from a material having memory so that the coupling retains its shape after installation into the mastoid cavity.
- 20 5. The implant package of any preceding claim, wherein the implant package is electrically coupled to the electrode array.
6. The implant package of any preceding claim, wherein the implant package is electrically coupled to the receiving and/or transmitting coil.
- 25 7. The implant package of claim 6, wherein the flexible connection includes one or more flexible arms containing leads which electrically connect the implant electronics to the receiving and/or transmitting coil.
8. The implant package of any preceding claim, wherein the implant package is a receiver-stimulator package for a cochlear implant.

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III. 1.III. 2.

INTERNATIONAL SEARCH REPORT

International application No.

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A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl. 7: A61F 11/04, 2/18

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHEDMinimum documentation searched (classification system followed by classification symbols)
A61F 2/IC, 11/ICDocumentation searched other than minimum documentation to the extent that such documents are included in the fields searched
AU: IPC AS ABOVE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 99/06108 A (ALFRED E MANN FOUNDATION FOR SCIENTIFIC RESEARCH et al) 11 February 1999 See page 3 lines 1-9, page 5 line 28-page 6 line 9 and page 20 lines 1-16.	1-3, 5-8
A	US 5814095 A (MULLER et al) 29 September 1998 See figures 1-4.	
A	US 5558618 A (MANIGLIA) 24 September 1996 See entire document.	

Further documents are listed in the continuation of Box C See patent family annex

* Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier application or patent but published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means		
"P" document published prior to the international filing date but later than the priority date claimed		

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Date of mailing of the international search report

10 OCT 2000

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU00/00936

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 97/05673 A (COCHLEAR PTY LTD) 13 February 1997 See entire document.	
A	WO 83/00999 A (HOCHMAIR) 31 March 1983 See entire document.	

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/AU00/00936

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report				Patent Family Member			
WO	9906108	AU	86804/98	EP	999874		
US	5814095	—	DE	19638158	EP	831673	DE
		19638159	EP	831674			
US	5558618	US	5906635				
WO	9705673	AU	31054/95				
WO	8300999	AU	88333/82	AU	89540/82	BE	894422
		BR	8207864	CA	1194552	DK	1993/83
		EP	76069	US	4419995		
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